and/or intrarectal use containing any protectant identified in § 346.14(a)(1), (2), (4), (5), (6), (7), and (9), and (b)(1), (2), (3), and (4), or any astringent identified in § 346.18(a) and (c). Apply to the affected area up to 6 times daily or after each bowel movement.

(9) *For products containing petrolatum or white petrolatum identified in § 346.14(a)(8) and (10).* Apply liberally to the affected area as often as necessary.

(e) The word ''physician'' may be substituted for the word ''doctor'' in any of the labeling statements in this section.

[55 FR 31779, Aug. 3, 1990, as amended at 59 FR 28767, June 3, 1994; 64 FR 13295, Mar. 17, 1999]

§ 346.52 Labeling of permitted combinations of anorectal active ingredients.

Indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity established in § 346.50(a). For a combination drug product that does not have an established name, the labeling of the product states the statement of identity established in § 346.50(a).

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the indication(s) for each ingredient in the combination, as established in the indications sections of this subpart.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings sections of this subpart.

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of this subpart. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

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Subpart C—Labeling

347.50 Labeling of skin protectant drug products.
347.52 Labeling of astringent drug products.
347.60 Labeling of permitted combinations of active ingredients.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 58 FR 54462, Oct. 21, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 347.1 Scope.

(a) An over-the-counter skin protectant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 347.3 Definitions.

As used in this part:

Astringent drug product. A drug product applied to the skin or mucous membranes for a local and limited protein coagulant effect.

Lip protectant drug product. A drug product that temporarily prevents dryness and helps relieve chapping of the exposed surfaces of the lips; traditionally called ''lip balm.''

Poison ivy, oak, sumac dermatitis. An allergic contact dermatitis due to exposure to plants of the genus Rhus (poison ivy, poison oak, poison sumac), which contain urushiol, a potent skin-sensitizer.

Skin protectant drug product. A drug product that temporarily protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli, and may help provide relief to such surfaces.

[68 FR 33376, June 4, 2003]

Subpart B—Active Ingredients

SOURCE: 68 FR 33377, June 4, 2003, unless otherwise noted.

§ 347.10 Skin protectant active ingredients.

The active ingredients of the product consist of any of the following, within the concentration specified for each ingredient:

(a) Allantoin, 0.5 to 2 percent.

(b) Aluminum hydroxide gel, 0.15 to 5 percent.

(c) Calamine, 1 to 25 percent.

(d) Cocoa butter, 50 to 100 percent.

(e) Cod liver oil, 5 to 13.56 percent, in accordance with §347.20(a)(1) or (a)(2), provided the product is labeled so that the quantity used in a 24-hour period does not exceed 10,000 U.S.P. Units vitamin A and 400 U.S.P. Units cholecalciferol.

(f) Colloidal oatmeal, 0.007 percent minimum; 0.003 percent minimum in combination with mineral oil in accordance with §347.20(a)(4).

(g) Dimethicone, 1 to 30 percent.

(h) Glycerin, 20 to 45 percent.

(i) Hard fat, 50 to 100 percent.

(j) Kaolin, 4 to 20 percent.

(k) Lanolin, 12.5 to 50 percent.

(l) Mineral oil, 50 to 100 percent; 30 to 35 percent in combination with colloidal oatmeal in accordance with §347.20(a)(4).

(m) Petrolatum, 30 to 100 percent.

(n) [Reserved]

(o) Sodium bicarbonate.

(p) [Reserved]

(q) Topical starch, 10 to 98 percent.

(r) White petrolatum, 30 to 100 percent.

(s) Zinc acetate, 0.1 to 2 percent.

(t) Zinc carbonate, 0.2 to 2 percent.

(u) Zinc oxide, 1 to 25 percent.

§ 347.12 Astringent active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

(a) Aluminum acetate, 0.13 to 0.5 percent (depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 0.13 to 0.5 percent aluminum acetate).

(b) Aluminum sulfate, 46 to 63 percent (the concentration is based on the anhydrous equivalent).

(c) Witch hazel.

§ 347.20 Permitted combinations of active ingredients.

(a) *Combinations of skin protectant active ingredients.* (1) Any two or more of the ingredients identified in §347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to §347.50(b)(1) and provided each ingredient in the combination is within the concentration specified in §347.10.

(2) Any two or more of the ingredients identified in §347.10(a), (d), (e), (g), (h), (i), (k), (l), (m), and (r) may be combined provided the combination is labeled according to §347.50(b)(2) and provided each ingredient in the combination is within the concentration specified in §347.10.

(3) Any two or more of the ingredients identified in §347.10(b), (c), (j), (s), (t), and (u) may be combined provided the combination is labeled according to §347.50(b)(3) and provided each ingredient in the combination is within the concentration specified in §347.10.

(4) The ingredients identified in §347.10(f) and (l) may be combined provided the combination is labeled according to §347.50(b)(7) and provided each ingredient in the combination is within the concentration specified in §347.10.

(b) *Combinations of skin protectant and external analgesic active ingredients.* Any one (two when required to be in combination) or more of the active ingredients identified in §347.10(a), (d), (e), (i), (k), (l), (m), and (r) may be combined